

Medication Safety Officer: Getting Started

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CHAPTER

1

"Medicine used to be simple, ineffective, and relatively safe. Now it is complex, effective, and potentially dangerous."

—Professor Sir Cyril Chantler¹

Introduction

The above statement by Professor Chantler can certainly apply to medication use today. The Institute of Medicine (IOM) Committee on Identifying and Preventing Medication Errors estimates a hospitalized patient experiences at least one medication error per day. Furthermore, the IOM reports at least 25 percent of all medication-related injuries are preventable. In the United States alone, at least 1.5 million preventable adverse drug events (ADEs) occur each year, at a cost of over 3.5 billion (2006) dollars.² Mortality rates attributed to ADEs range between 1 and 2.45 percent.^{3,4} The imperative for action to prevent harm related to medication use is undeniable.

"The foundation of a successful medication safety program is a dedicated, willing pharmacist leader."⁵ This premise is supported by the IOM, the National Quality Forum (NQF), and the American Society of Health-System Pharmacists (ASHP).^{2,6,7} A leader committed to advancing medication safety will deliver the focus and expertise necessary to enhance an organization's patient safety outcomes. The medication safety officer (MSO), a position dedicated to patient safety efforts to reduce the risks of medication use, will fulfill this essential role.

Scope of Practice

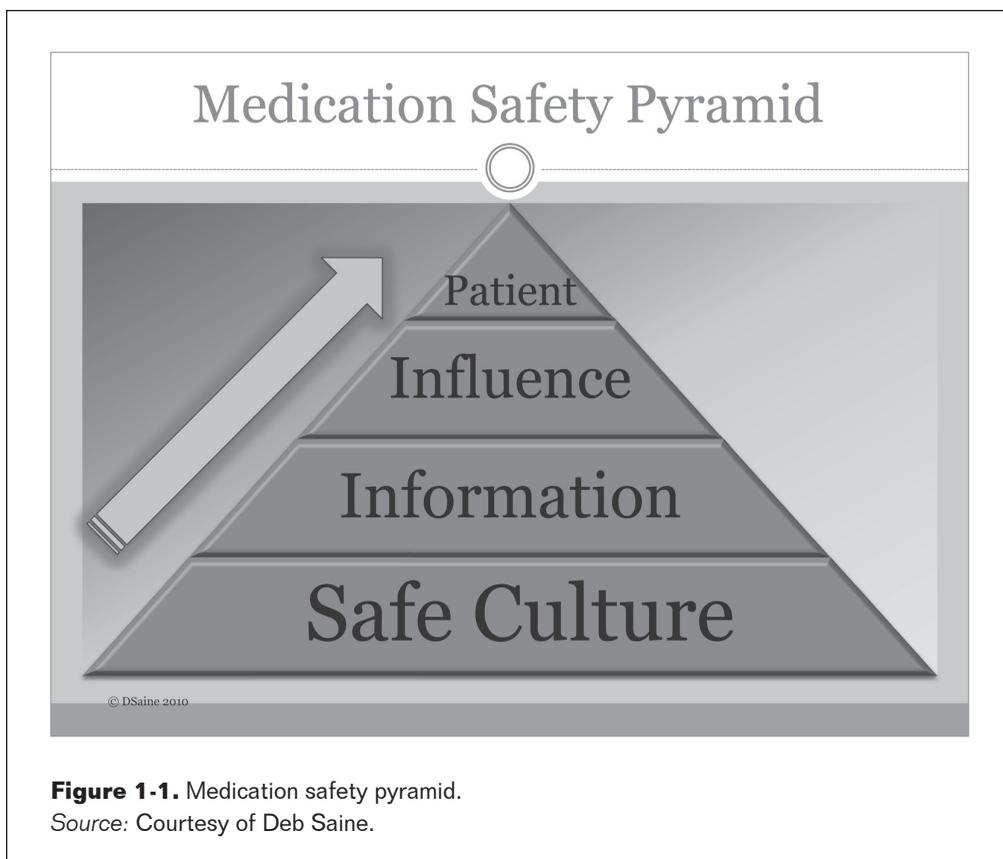
What are the expectations and the boundaries for the MSO's work? In the chapter "Action Agenda for Health Care Organizations," the IOM Committee on Identifying and Preventing Medication Errors recommends "advocate for a medication safety officer with responsibility for improving medication safety throughout the hospital."² The NQF-endorsed practice 18 objective states, "Pharmacy leadership structures and systems ensure a multidisciplinary focus and a streamlined operational approach to achieve organization-wide safe medication use."⁶ The ASHP Statement on the Role of the Medication Safety Leader provides an excellent concise overview of the MSO role (see Appendix 1-A). The statement asserts, "The scope of a medication safety leader's responsibilities reaches into every corner of the health-care system and encompasses many roles, such as educator, preceptor, mentor, detective, compliance officer, risk manager, engineer, accountant, statistician, computer analyst, and counselor."⁷ The MSO's scope is comprehensive, intended to span the entire medication-use process as practiced by every participant discipline, across the entire organization.

Stated simply, the MSO's mission is to prevent patient harm. Consider the National Patient Safety Foundation's (NPSF) statement "Patient safety has to do primarily with the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care itself."⁹ Note that the emphasis of safety is on *outcomes*, rather than concentrating on *preventing errors*. This is a key concept for the MSO to understand. The MSO's mission, then, may be focused to state: avoid, prevent, and ameliorate adverse outcomes or injuries (e.g., patient harm) stemming from the medication-use process. The *medication-use process* includes procedures and systems used to provide medication therapy to patients such as medication procurement, storage, prescribing, transcribing, preparing, dispensing, administration, documentation, and monitoring. This mission frames the overarching goal and guides the MSO's decisions and actions.

The NPSF further recognizes that safety " . . . is more than the absence of adverse outcomes and it is more than avoidance of preventable errors or occurrences. Safety does not reside in a person, device, or department."⁹ This correlates well with the MSO's broad scope of practice in medication safety, as described above. The MSO must also address issues and occurrences encompassing errors and deviations, risky situations, and near-misses, as well as events resulting in adverse outcomes. To improve safety, the MSO will explore relationships between systems and their elements.

The MSO's approach to medication safety may be portrayed as a pyramid (see Figure 1-1). In a broad sense, it describes the MSO's activities in pursuit of his or her mission. The levels of the pyramid are not mutually exclusive, as the MSO will be addressing multiple issues concurrently. This short discussion provides an overview of the tactics used by the MSO; concepts and specific MSO actions are presented in more detail in subsequent chapters.

A successful medication safety program depends on the presence of a *safe culture*.^{2,5,6,10-12} Culture is so vital to improving safety that it tops the lists of the "Model



Strategic Plan for Medication Safety¹³ and the Agency for Healthcare Research and Quality's (AHRQ) "30 Safe Practices for Better Health Care."¹⁴ Developing and enhancing a culture in which medication safety thrives are fundamental to the MSO's functions—thus, they comprise the base of the pyramid. When possible, the MSO should try to integrate strategies to enhance the culture of safety with other tasks or responsibilities. Perspectives on culture and the MSO's role are described in Chapter 5.

The next section of the pyramid, *Information*, reflects the MSO's use of internal and external information, and information on standards of care to direct his or her activities. "Strategic goals related to medication safety should be based on an assessment of internal medication-use processes and capabilities, external influences on medication safety, patient needs, and the health care marketplace as it relates to medication use."¹⁵ MSOs must strive to understand the nature of events and the safety environment in their own organizations to prioritize and strategize actions to improve safety.^{7,10-13, 16,17} At the same time, it is essential for the MSO to develop and maintain medication safety expertise through continuous professional development, and awareness of external events and developments in the patient safety field.⁷ Michael Cohen, President of the Institute for Safe Medication Practices, points out the importance of this by observing "Unfortunately, there are too many in health

care who feel that if it hasn't happened to them, the adverse experiences of others do not apply." The MSO should also be familiar with standards of care as a basis for medication safety enhancement. Examples include the best practice recommendations of professional organizations (e.g., ASHP), accreditation standards (e.g., The Joint Commission), and other standards-setting agencies (e.g., Centers for Disease Control and Prevention). Chapter 2 begins to discuss these concepts in more detail.

Moving up the pyramid, it is time for action: *Influencing Practice Change*. With little to no authority over the many disciplines and departments participating in the medication-use process across the organization, the MSO cannot simply "command" a transformation, and expect it to occur. As the MSO, you must combine leadership skills, medication safety expertise, experience in performance improvement methods, and teamwork to influence practice changes to improve safety.⁷ Influencing change is one of the most challenging aspects of the MSO's role and is addressed in Chapter 3. Collaboration is essential to improving safety.^{5,6,11,12,18,19} Through culture change and use of information and data, the MSO must shape and guide medication safety ventures, *must influence them*, to reach the pinnacle of the pyramid: *Patient Safety*.

The patient is placed at the top of the pyramid, as the subject of the MSO's primary goal: patient safety, keeping the patient safe from harm. It emphasizes the patient-centered mission of the MSO. The commitment we make to patient safety must be explicit and visible in the organization—the highpoint, or the top, of the pyramid.

Job Description

The MSO is "a clinical practitioner designated by an organization to serve as the authoritative expert in safe medication use."⁷ Other titles used to describe this role include medication safety leader, medication safety manager, medication safety coordinator, medication safety clinical specialist, medication safety pharmacist, and director of medication safety. A job description will help communicate the vision for this role, expectations for performance, and the relationships to others within the organization. It also serves as a written document to describe responsibilities, qualifications, and reporting relationships and is typically required during development of a new MSO position. Reviewing existing job descriptions can also be helpful when updating or enhancing the MSO's role. The intent of this chapter is to give a general sense of the scope and intent for this position, with the understanding that the culture and organizational structure will directly impact the responsibilities and opportunities for the MSO. When considering this position's scope of responsibilities as you develop a proposal to administration, you will wonder how you managed to get along without this dedicated person!

Reporting Structure

The MSO may serve an individual hospital, a group of organizations at a health system level, or a more diverse collection of organizations at a corporate level. Reporting structures vary for the MSO, as the position continues to evolve within health

care organizations. At hospital or health system settings, the MSO most commonly reports to one of four areas: Pharmacy, Patient Safety/Risk Management, Quality Improvement, or a senior administrator (e.g., vice president, chief medical officer). Because the MSO's reporting process depends a great deal on the organization's culture, structure, and hierarchy, there could be more than one reporting line. While the optimal placement has not been studied, there are some factors for consideration.

Patient safety, the freedom from accidental injury due to medical care or medical errors⁸—is an essential organizational priority. Medication safety, which may be defined as the freedom from accidental injury due to medical care or medical errors *during the medication-use process*, deserves the same prioritization, given the scope of medication use in patient care and the frequency and severity of potential harm. It follows that the MSO should be placed high in the organizational chart to work collaboratively with the patient safety officer (PSO). Reporting to senior leadership offers the MSO the attendant authority and empowerment to facilitate change. This also allows the MSO to align concerted safety efforts with other key leaders, such as the chief nursing officer (CNO), chief pharmacy officer (CPO), and chief executive officer (CEO). A suggested structure for this paradigm is shown in Figure 1-2.

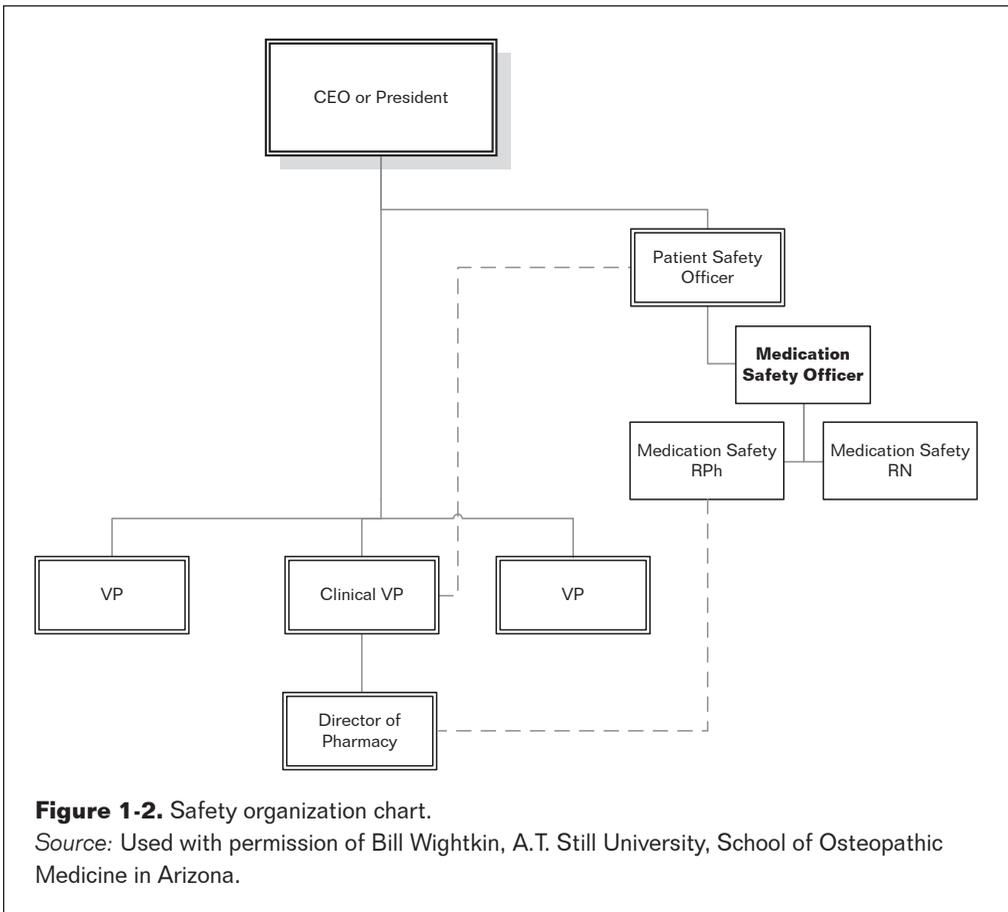


Figure 1-2. Safety organization chart.

Source: Used with permission of Bill Wightkin, A.T. Still University, School of Osteopathic Medicine in Arizona.

Within a department, a position generally has a direct report based on the specific department's hierarchy. An MSO based in a department most often reports to the director or leader of that area. In the pharmacy department, it is common for the MSO to report to the director of pharmacy. Other department leaders for MSO reporting include the director of quality and safety or the director of performance improvement. Some MSOs report to leadership at the vice president level, gaining strategic advantages discussed above.

There are potential benefits (and conversely, challenges) for the MSO reporting structure within or external to the pharmacy department.

Potential benefits of reporting within the pharmacy department include:

- Elevated attention to medication safety through MSO involvement in department leadership, operations, clinical services, and business decisions
- Enhanced understanding of pharmacy operations by MSO and ability to design safety systems and resolve identified risks
- Close working relationships with pharmacy staff
- Increased access by pharmacy department to MSO expertise

Potential benefits of reporting outside the pharmacy department include:

- Fosters an interdisciplinary approach to medication safety
- Eliminates conflicts of interest with departmental agendas, such as financial or production decisions
- Freedom from daily pharmacy operational responsibilities
- Removes potential for medication safety focus to be diverted to staffing duties
- Enhances MSO's understanding of the perspectives and roles of other disciplines
- Increases access by external departments to MSO expertise

Because of the overall responsibility for oversight of the medication-use system, the MSO may have additional reporting lines. For example, you may have a primary (or solid line) reporting relationship with the director of pharmacy, with secondary (or dotted line) reporting to the director of performance improvement. Matrix reporting is often a reflection of the organization's management philosophy and its patient safety structure.

A committee structure, more thoroughly discussed in Chapter 2, should be in place to directly oversee the medication-use systems in the organization. As the MSO, you should take a leadership role on this committee, generally referred to as the Medication Safety Committee (MSC). The MSC should report to the Pharmacy and Therapeutics (P&T) Committee, as a subcommittee charged with ensuring medication safety throughout the organization. The P&T also has responsibility to medical staff leadership to keep physician leadership informed of P&T activities, and they may solicit feedback from that group prior to making decisions that could impact physician practices (e.g., therapeutic interchanges). Another reporting line

could be the organization's Patient Safety Committee or other similarly named committee (e.g., Safety Council).

Authority

Overall, the most important aspect of any type of structure is to make sure identified problems/issues are brought to the attention of the appropriate level of authority. For you to be effective in this role, it is critical to establish a sufficient level of authority. The MSO must have the support of the organization's administration to conduct investigations, interview staff, and coordinate process improvement activities. A close relationship with the Safety/Risk Management department would help to facilitate these types of activities. Safety/Risk Management is generally the department that has responsibility for coordinating patient safety investigations, and the MSO should be the primary authority on incidents involving medications. A committee structure is best for authorizing and approving process improvements and final action plans, and the MSC would be the appropriate multidisciplinary committee. Committee involvement is discussed in Chapter 2.

Responsibilities

Regardless of organizational structure, this position involves a wide variety of activities. There will be general day-to-day activities related to review and investigation of reported medication errors and then time-specific activities related to oversight of the medication system utilizing an MSC. In general, any activities related to medication use should be considered under the MSO's jurisdiction. Even though this concept seems obvious, medication-use discussions can take place in a myriad of settings within an organization without the MSO's knowledge. It becomes important then for the MSO to have knowledge of critical medication-use activities. Some are obvious, some not. The entire medication-use process, comprised of formulary system, storage, ordering, verification, preparation, dispensing, and administration and monitoring, has potential safety issues.

Medication-use discussions within the organization include traditional committee structures sanctioned by the medical staff and other ad hoc or work-groups for specific projects. Some organizations are good at identifying committee charges/activities and communicating this information to key stakeholders so it is important to know your organization's culture and communication style. The depth of the MSO's activities in any given situation or medication-related committee may depend on the workload or the group's representation. You may find your participation in various meetings may be frequently requested. Prioritization is important in determining what activities to participate in as it is difficult, if not impossible, to be involved in every meeting. In a process where roles and responsibilities are clearly defined, the MSO may be able to provide a consultation instead of direct participation.

The MSO's responsibilities may be categorized in five broad areas: leadership, medication safety expertise, influencing practice change, research, and education.⁷

The details for each section may be found in Appendix 1-A. A summary of responsibilities within each area follows.

Leadership

- Establish the vision for a safe medication use system
- Develop the medication safety plan
- Lead activities to achieve the vision and plan
- Support and enhance a culture of safety

Medication Safety Expertise

- Serve as expert resource for medication safety
- Recommend safe systems design, including technology and practice changes
- Facilitate management of medication-related risks and adverse events
- Lead medication safety committee

Influencing Practice Change

- Foster a comprehensive and interdisciplinary approach to medication safety actions
- Collaborate with departments and groups to apply risk reduction strategies
- Align and integrate medication safety into the organization's strategic plan
- Employ quality improvement methodologies to improve processes

Research and Education

- Participate in external event reporting programs
- Integrate medication safety into orientation and training for all providers
- Conduct research and contribute to literature on medication safety
- Educate colleagues, students, residents, and other health care professionals

Job descriptions often call for a more granular description of responsibilities, activities, or tasks. Key activities for the MSO include the following:

- Reviews and analyzes medication errors and ADEs
- Ensures compliance with medication safety regulations and standards
- Serves as chair for the MSC
- Serves as a resource to the organization and community on medication safety matters
- Assists in the development and review of medication-use pharmacy and hospital- and system-level policies, and their implementation
- Guides the design, implementation, and maintenance of safe medication systems in the organization

- Monitors the external environment for best practices and evaluates them for implementation in the organization
- Provides direction for prioritization of the organization's medication system improvement projects
- Facilitates or develops a structured approach for employee orientation and training for pharmacy staff and others involved in the medication-use process related to medication safety as it applies to the specific job category
- Provides ongoing medication safety education for pharmacy staff and other health care professionals to promote safe medication practices
- Facilitates availability of educational programs and materials to improve medication safety and regulatory compliance
- Participates in departmental and interdisciplinary hospital, health system, and regional committees related to emergency medications, drug shortages, adverse events, medication errors, policy review, technology, safe medication use, and patient safety
- Analyzes current medication-use practices that may contribute to medication errors using quality improvement methodologies, facilitates process and system changes to reduce the likelihood of occurrence/recurrence of error

A review of 30 job descriptions dated between 2002 and 2012 for hospital or health-systems MSOs revealed that expectations continue to evolve. Activities related to enhancing or building a *Just Culture* (see Chapter 5 for more discussion of *Just Culture*) and participation in technology planning and safety assessments were more likely to be found in more recent job descriptions than earlier examples. Recent job summaries reflected a more comprehensive approach to the position. The range of hospital or health-system experience listed in job qualifications ranged from 0 to 10 years, with a median of 5 years. Sample job descriptions are provided in Appendix 1-B. Appendix 1-C demonstrates alignment of MSO responsibilities with an organizational strategic plan.

Attributes of the MSO

Possession of certain attributes will improve the MSO's effectiveness. Your strengths should include the abilities to anticipate error and hazards and mitigate potential harm. A wide variety of skills is necessary to hone these abilities, including cognitive skills, such as situational awareness, and social/interpersonal skills, such as teamwork.²⁰ Attributes for success^{7,20-22} may be categorized as knowledge, skills, and abilities (KSAs), and are presented below. In this format, *knowledge* refers to the understanding of an organized body of information; *skills* denote proficiency or expertise in the subject matter; and *abilities* signify the capacity to perform an activity or task. As a current or prospective MSO, you will benefit from evaluating your KSAs for professional development opportunities.

Knowledge

The MSO should have a broad understanding of:

- All aspects of the medication-use system
- Health care technologies used in the medication-use process
- Pharmaceutical care
- Clinical expertise
- Culture of safety, Just Culture concepts
- Change management concepts
- Holistic nature of health care systems
- Concepts of risk and prioritization, statistics, population data
- Performance improvement methodologies and tools
- Framework for human error
- Basic principles of human factors
- Medication safety resources
- Standards of practice related to medication use
- Accreditation process, standards, and regulations

Skills

The MSO should demonstrate excellence in the following skills:

- Leadership
- Verbal communication and presentation (small and large group)
- Written communication, editing
- Active listening
- Time management
- Project management
- Analytical
- Safe system/process design

Abilities

The MSO should possess the ability to perform the following:

- Facilitate practice change
- Collaborate with staff at all levels
- Effectively provide education
- Synthesize solutions
- Apply standards of practice to improve safety
- Apply defined strategies and protocols
- Function proactively vs. reactively
- Write clear and concise policy and procedures

- Recognize risks, anticipate errors
- Analyze systems and evaluate data

Education and Professional Development

During the evolution of the MSO position (early 1990s to early 2000s), those serving as MSOs relied largely on health care system experience, continuing education offerings, and mentorship to build their expertise. Medication safety is now part of didactic and experiential education, with diverse professional development offerings for practitioners in a variety of disciplines. As the field remains quite dynamic, this section gives a general overview of possibilities, and the reader is encouraged to seek current information at the time of reading.

Topics related to medication safety are integrated into accredited Doctor of Pharmacy degree programs through the core curriculum and pharmacy practice experiences. The Accreditation Council for Pharmacy Education (ACPE) lists “medication safety” as a distinct clinical science section in its 2011 curriculum guidance document.²³ Safety topics include causes of medication errors, systems approaches to medication errors, human factors, error reduction strategies, pharmacy leadership in medication safety, and quality improvement methods. ACPE also suggests that students should participate in identifying and reporting medication errors and adverse drug reactions and participate in activities regarding accreditation and regulatory safety requirements during their advanced pharmacy practice experiences (APPEs).

The ACPE notes that separate medication safety courses are not mandated, but the expectation is that the subject matter be addressed adequately in the curriculum. Some schools provide dedicated medication safety courses and may include opportunities for advanced practice experiences to strengthen the foundation in medication safety. Although the Doctor of Pharmacy graduate should be familiar with medication safety concepts, the content, intensity, and depth of this medication safety education is not adequate to prepare the graduate for the MSO position.

All ASHP postgraduate year one (PGY1) residency programs include an educational outcome related to medication safety.²⁴ This gives the resident opportunities for deeper understanding of medication safety principles, and to actively participate in an organization’s improvement activities. Preceptors may include discussions of concepts such as system error, process-mapping, error categorization, human factors, and Just Culture. The goals, objectives, and in particular, the instructional objectives, articulated in the ASHP accreditation standard requirements provide guidance to develop an effective introduction to medication safety for the resident.

Completion of a postgraduate year two (PGY2) pharmacy residency in medication-use safety is recommended for those interested in becoming an organization leader in this area. Based on the outcomes of this program, graduates will be qualified to:²⁴

- Function as an effective leader for medication-use safety

- Serve as an authoritative resource on medication-use safety for the organization
- Develop a vision of an ideal safe medication-use system for the organization
- Represent the medication-use safety perspective to the organization's design of its technology and automation systems
- Conduct planning for the pursuit of the organization's vision of a safe medication-use system
- Collect medication-use data and use appropriate data analysis techniques to identify needed improvements in the medication-use system
- Manage changes in the medication-use system
- Conduct medication-use safety research

Formal programs, such as fellowships, offer intensive learning experiences related to medication safety. While some concentrate on medication safety, others may provide a more broad perspective in patient safety. A summary of programs currently available is provided in Table 1-1.

Demonstration of competency may be identified through credentialing programs. The American Society of Medication Safety Officers (ASMSO) has announced the Board Certified Medication Safety Specialist (BCMSS) credential, with the first examination to be available in 2013.²⁵ The BCMSS establishes core competency domains for medication safety, and sets an expected proficiency level. It also strives to validate a candidate's medication safety knowledge and skill set for employers. The National Association for Healthcare Quality (NAHQ)'s Certified Professional in Healthcare Quality (CPHQ) is another certification program of interest for the MSO.²⁶ Although not specific to medication safety, the content outline for CPHQ certification addresses many MSO tasks and responsibilities such as leadership, information management, quality improvement and patient safety. The Certified Professional in Patient Safety (CPPS) credential identifies professionals competent in patient safety science and human factors engineering who can effectively plan and implement patient safety initiatives. The Certification Board for Professionals in Patient Safety (CBPPS), established by the NPSF, oversees this credentialing process.²⁷

Continuing education (CE) programs on various aspects of medication safety have proliferated within the last decade. This may be related to increased interest in safety and related research and publications, primed by the 2000 IOM report "To Err is Human: Building a Safer Health System" and those published subsequently. The field of patient safety, including medication safety, has snowballed, with increased attention by accrediting organizations. Some states now require a defined number of hours of CE in medication safety for relicensure. The Accreditation Council for Pharmacy Education (ACPE) CE Universal Activity Number topic designator "05" indicates the program is related to patient safety. CE programs are provided in a number of formats, encompassing home study and live presentations via teleconference, webinar, and meetings.

Table 1-1. MSO Professional Development Programs

Program	Duration	Focus	For More Information
Medication Safety Pharmacy Fellowship at Saint Vincent Hospital/MCPHS	24 months	Medication safety, education, and clinical research	http://www.stvincenthospital.com/professionals/pharmacy-fellowship.aspx
Purdue University Community Practice Research Fellowship Program/MS in Pharmacy Practice with an Emphasis in Medication Safety	24 months	Medication safety; community pharmacy services	http://www.phpr.purdue.edu/residencies/snyder.pdf
ISMP Safe Medication Management Fellowships	12 months	Medication safety	http://ismp.org/profdevelopment/managementfellowship.asp
FDA/ISMP Safe Medication Management Fellowship	12 months	Medication safety; regulatory experience	http://ismp.org/profdevelopment/fdaismpfellowship.asp
AHA-NPSF Comprehensive Patient Safety Leadership Fellowship	12 months	Patient safety; transformational change	http://www.hpoe.org/PSLF/PSLF_main.shtml
ISMP International Mentorship Program	4 weeks	Group and individual learning projects (international participants travel to U.S.)	http://ismp.org/Consult/internationalExperience.asp
IHI Patient Safety Executive Development Program	7 days	Patient safety leadership	http://www.ihl.org/offers/Training/PatientSafetyExecutive/2013patientsafetyexecutivedevelopment/Pages/default.aspx
ISMP Practitioner in Residence Program	5 days	Individualized program - medication safety	http://ismp.org/Consult/practitioner.asp
UW Systems Engineering Initiative for Patient Safety Short Course	4-5 days	Applies engineering approaches to patient safety	http://cqpi.engr.wisc.edu/shortcourse_home
ISMP Medication Safety Intensive	2 days	Medication safety; medication safety oversight	http://ismp.org/educational/MSI/default.asp

ISMP, Institute for Safe Medication Practices; FDA, Food and Drug Administration; AHA, American Hospital Association; NPSF, National Patient Safety Foundation; IHI, Institute for Healthcare Improvement; MCPHS, Massachusetts College of Pharmacy and Health Sciences; UW, University of Wisconsin.

Education and professional development opportunities include college of pharmacy curricula, postgraduate programs, intensive options, and CE offerings. MSOs are encouraged to use information in the responsibilities and attributes sections to assess areas for professional development, and to seek opportunities to meet those needs. In turn, the MSO should endeavor to inspire every practicing pharmacist to engage in medication safety professional development.

Summary

The MSO position is critical for enhancing medication safety in an organization. Their leadership encompasses the entire medication-use process across the organization. A pyramid approach incorporating safe culture, use of information, and influencing change may be used to reduce patient harm related to medication-use. The position must be structured to ensure comprehensive scope and adequate authority to carry out responsibilities in areas of leadership, medication safety expertise, influencing practice change, research and education. Self-assessment of key attributes and ability to perform MSO job responsibilities should be used to drive professional development. By effectively identifying and addressing medication safety concerns and proactively providing direction to safeguard the medication-use system, the MSO will be an organization's highly valued asset. This position's challenges will be considerable, but the rewards of making important changes that improve the safety and well-being of patients and staff are immeasurable.

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Appendix 1-A

ASHP Statement on the Role of the Medication Safety Leader

Position

The American Society of Health-System Pharmacists (ASHP) believes that medication safety is a fundamental responsibility of all members of the profession of pharmacy. For a medication safety program to succeed, however, it is essential that there be an innovative leader to set a vision and direction, identify opportunities to improve the medication-use system, and lead implementation of error-prevention strategies. The medication safety leader's role includes responsibility for leadership, medication safety expertise, influencing practice change, research, and education. ASHP believes that because of their training, knowledge of the medication-use process, skills, and abilities, pharmacists are uniquely qualified to fill the roles and meet the responsibilities of the medication safety leader in hospitals and health systems.

Background

Hospital and health-system pharmacists have improved pharmacy systems over the past 60 years to reduce the risk that medications could harm patients. Medication safety was at the heart of such historic innovations in pharmacy services as unit-dose systems, decentralized clinical pharmacy services, and intravenous admixture services. The crucial leadership role of pharmacists in medication safety has been summarized as follows:

Pharmacy leadership is the core of a successful medication safety program. Pharmacy leaders can play an enormously important role in performance improvement. They can be part of the senior leadership team's DNA because their impact and view go far beyond the walls of the pharmacy.... Pharmacists can play an important role as leaders to reduce patient safety risks, optimize the safe function of medication management systems, and align pharmacy services with national initiatives that measure and reward quality performance.¹

The landmark Institute of Medicine (IOM) report *To Err is Human: Building a Safer Health System*² generated major patient safety initiatives by government agencies, regulatory and accrediting bodies, professional and organizational associations, and health care organizations. The Joint Commission (TJC) National Patient Safety Goals (NPSGs)³ are an example of a response to the original IOM report. The Pharmacy Practice Model Initiative (PPMI)⁴ and the National Quality Forum (NQF) Safe Practice 18⁵ incorporate medication safety principles to ensure optimal patient safety and outcomes.

The medication safety leader (also referred to as a medication safety officer, medication safety manager, or medication safety coordinator, among other titles) is a clinical practitioner designated by an organization to serve as the authoritative expert in safe medication use. Traditionally, the medication safety leader has been a clinical pharmacist or manager within the department of pharmacy, although the

position is sometimes filled by a nurse or physician. The medication safety leader may report to the organization's risk management department, its office of quality, or to a senior administrator (e.g., hospital vice president, chief medical officer, or chief executive officer). Reporting outside the pharmacy department may foster interdisciplinary approaches to medication safety. Medication safety leadership may encompass a single hospital or a group of organizations (e.g., spanning a health system or at a corporate level of a larger organization). Regardless of organization size, it is critical that the fundamentals of medication safety are the central component of the medication safety leader's job function. Although medication safety leaders may have other responsibilities in smaller institutions, medication safety should remain their core responsibility, and they must be strategically positioned and empowered to lead efforts to reduce the risks of medication use.

The characteristics of a medication safety leader include:

1. A strong understanding of the facility's internal systems and processes developed through firsthand experience, observations, medication-use evaluations, interviews, and data analysis for a spectrum of patient populations (e.g., pediatric, geriatric, cardiac, oncology).
2. Clinical expertise and a broad understanding of health care systems and processes to facilitate accurate interpretation of clinical events.
3. Knowledge of and experience with all aspects of the medication-use system, including procurement, prescribing, transcribing, preparation, distribution, administration, documentation, and monitoring.
4. Strong analytical skills and an understanding of statistics, population data, and the concepts of risk and prioritization.
5. Knowledge of performance improvement methodology and tools, including root cause analysis (RCA), failure mode and effects analysis (FMEA), cause-and-effect diagramming, process-flow mapping, and methods for monitoring projects and measuring the progress of performance improvement initiatives.
6. Three or more years of post-training health-system practice experience.
7. Demonstrated leadership skills.
8. Excellent small and large group presentation skills.
9. Excellent verbal communication skills, especially the ability to communicate to all types of health care providers, as individuals as well as in small and large groups.
10. Excellent writing and editing skills.
11. Strong personal belief that resolving the problem of medication errors is a systems issue and not an individual health care provider issue.
12. Ability to function proactively rather than reactively.
13. Strong personal belief in the concept of a "just culture"⁶ that enhances transparency, opens participation to all health care professionals, and

fosters a "lessons learned" environment in an organization's medication-error reporting system.

14. Understanding of concepts and application of safety principles, continuous quality improvement, and human factors engineering.
15. Appropriate assertiveness.
16. A passion for medication safety and improving patient outcomes.
17. Proven success in working with interdisciplinary teams and engaging diverse groups.
18. Strong personal belief in engaging patients as part of the health care team.
19. Eagerness to learn from events outside one's own facility (e.g., through external sources of information) to apply learning about what went wrong in order to identify and remedy possible system weaknesses to prevent patient harm.⁷

The scope of a medication safety leader's responsibilities reaches into every corner of the health care system and encompasses many roles, such as educator, preceptor, mentor, detective, compliance officer, risk manager, engineer, accountant, statistician, computer analyst, and counselor. A typical day may include attending safety rounds, precepting pharmacy students and residents, writing policies, reviewing adverse drug reactions and medication error reports, developing error-prevention strategies, leading process improvement teams, implementing action items, reviewing smart pump libraries, ensuring safe use of automated medication dispensing systems, assessing the safety of replacement drug products during drug shortages, orienting new professional staff, assisting with medication reconciliation, conducting tracers to ensure compliance with accreditation standards (e.g., TJC medication management standards and NPSGs), working with practitioners to resolve acute events, attending medical staff meetings, or educating the corporate board on the culture of safety. Most medication safety leaders quickly find themselves involved in many projects and committees as well as serving as the contact person when nursing, pharmacy, or medical staff have questions or problems. The medication safety leader needs a solid understanding of patient safety principles and must have the ability to prioritize work activities to have a positive impact on the safety of patient care. The medication safety leader should strive to acquire additional skills crucial to success, such as presentation and communications skills, as well as expertise in process improvement methodologies such as Six Sigma and Lean. Formalized training in medication safety can be achieved through residency, fellowship, certificate programs, and other methods of continuing education. ASHP supports the expansion of pharmacy education and postgraduate residency training to include an emphasis on medication safety.⁸

Responsibilities of Medication Safety Leaders

Medication safety leaders must collaborate with all types of health care professionals, support staff, and management, and consider all components of the medication-use process in both inpatient and clinic settings in order to improve medication safety.

The medication safety leader's role includes responsibility for leadership, medication safety expertise, influencing practice change, research, and education.

Leadership. To provide leadership, the medication safety leader will:

1. Develop a vision of an ideal safe medication-use system for the organization.
2. Oversee the planning, creation, review, and refinement of a medication safety plan.
3. Proactively develop and lead implementation of error-prevention strategies based on practice standards, literature review, medication safety tools, and analysis of the organization's medication safety data.
4. Participate in the planning, design, and implementation of the organization's medication-use technology and automation systems.
5. Build a culture of safety through "lesson learned" education and communication across the entire organization.
6. Oversee processes to collect information on the organization's medication errors and system failures to ensure that they are captured and barriers to reporting are addressed.
7. Ensure compliance with state and federal regulatory and legal requirements relating to medication safety, and assist in the accreditation process by ensuring that the organization's medication-use processes meet applicable medication management standards and NPSGs.

Medication Safety Expertise. In the role of medication safety expert, the medication safety leader will:

1. Serve as an authoritative resource on medication safety for the organization.
2. Contribute the medication safety perspective for technology initiatives.
3. Contribute the medication safety perspective to internal and external emergency preparedness planning.
4. Serve as an internal consultant to investigate medication safety events or issues and develop recommendations for action.
5. Serve as the chair of the Medication Safety Committee, whose duties may include setting the agenda, reviewing general and specific error reports, and examining the progress of projects and initiatives assigned to the medication safety team.
6. Be knowledgeable in the application and use of a variety of quality improvement methodologies and tools (e.g., FOCUS-PDCA or Lean methodologies, root cause analysis, failure mode and effects analysis).
7. Collect, review, and analyze, as the leader of review teams, the organization's medication-use, medication error, adverse drug reaction, and continuous quality improvement data (e.g., markers of adverse drug events, smart pump event data, triggers and surveillance information, and auto-

- mated dispensing system and bedside barcode scanning reports) and use appropriate data analysis techniques to identify needed improvements and develop high-leverage error-reduction strategies.
8. Predict and prepare to manage medication safety issues caused by potential or actual drug product shortages and the use of replacement drug products.
 9. Maintain knowledge of trends and developments in the patient safety field through continuous professional development; reading articles, journals, and related material; attending appropriate seminars, conferences, or educational programs; and utilization of information from the Institute of Safe Medication Practices (ISMP) National Medication Error Reporting Program, the Food and Drug Administration (FDA) Med-Watch program, and similar programs.
 10. Participate at a local and national level in patient safety and medication safety organizations and initiatives.

Influencing Practice Change. To influence practice change, the medication safety leader will:

1. Collaborate with other departments (e.g., pharmacy, risk management, and patient safety), hospital or health-system senior leadership, frontline staff, and nursing and medical staff leadership to identify and prioritize safety issues and develop risk-reduction strategies using the methods listed above to identify opportunities to improve medication safety.
2. Manage changes in the medication-use system to enhance medication safety, ensure that appropriate measures are taken to address and resolve medication safety issues, and see that hospital staff and faculty are supported in providing safe care for patients.
3. Work closely with others (e.g., the patient safety officer) to integrate medication safety into the overall strategic plan for patient safety and coordinate medication safety initiatives with organizational patient safety initiatives.
4. Participate in or lead multidisciplinary hospital and health-system committees concerned with medication errors, adverse drug events and reactions, near misses, policy review, safe medication use, new product review, and patient safety to identify risk points and prioritize system improvements to reduce the potential for medication error and patient harm.
5. Consult with and advise specific clinical teams and the hospital and health system generally on opportunities and strategies to improve patient care.
6. Encourage organization-wide medication error reporting through an established and accepted error reporting system that utilizes appropriate error detection methods (e.g., trigger tools) and through other appropriate avenues such as the Pharmacy & Therapeutics Committee, Medication Safety Committee, or Patient Safety Committee.

7. Develop effective methods for spreading best medication-use practices throughout the organization.
8. Use continuous quality improvement principles to assess and report on the status of efforts to improve medication safety.
9. Periodically review and update clinical decision support tools to alert staff to high-risk situations and educate staff as needed.

Research and Education. To further research and education regarding medication safety, the medication safety leader will:

1. Design and assist in the implementation of education and orientation programs in safe medication use, including:
 - development of competency assessment for staff tasks related to medication safety (e.g., use of smart pumps and automated medication dispensing systems);
 - education of health care providers, other pertinent staff, and (as possible) patients to ensure they are competent in safe medication-use practices; and
 - provision of effective ongoing programs and presentations related to safe medication use to diverse audiences (e.g., nursing, pharmacy, respiratory care, and medical staff).
2. Share information about actual or potential medication errors or harm with safety organizations such as the Institute for Safe Medication Practices (ISMP), the FDA, drug or product manufacturers, and state error reporting programs.
3. Conduct medication-use safety research through well-designed, externally validated studies, and implement evidence-based practices for medication safety.
4. Contribute to the literature on medication safety.
5. Provide medication safety education to pharmacy colleagues, students, and residents, as well as other health care professionals.
6. Integrate medication safety into orientation and training for all health care providers who participate in the medication-use process.

Conclusion

ASHP believes that pharmacists, as experts on medication use, are uniquely qualified to serve as medication safety leaders. Medication safety leaders articulate the vision and direction for improving the safety of the medication-use system to prevent patient harm. The medication safety leader's role includes responsibility for leadership through direction and prioritization, medication safety expertise, influencing practice change, research, and education. Through analysis of the organization's medication safety data and literature review, the medication safety leader will lead development and implementation of proactive error-prevention strategies and build a culture of safety across the organization.

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Web Resources

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www.ismp.org

www.safemedication.com

www.asmpo.org

www.ahrq.gov

<http://www.fda.gov/cder/drugSafety.htm>

www.ihp.org

http://www.jointcommission.org/standards_information/npsgs.aspx

<http://www.leapfroggroup.org/>

www.qualityforum.org

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www.usp.org

<http://www.patientsafety.gov/>

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Appendix 1-B

Sample Job Descriptions

JOB DESCRIPTION #1

Medication Safety Officer

Position Summary

Provides a leadership role in formulating policy and instituting models that promote medication safety in all aspects of the medication management process. In conjunction with designated facility leadership, the role is responsible for coordinating all activities related to medication safety provided by the facility. These activities involve reporting, system and process evaluation, formulation of recommendations and initiatives, coordination of intervention strategies, and monitoring of activities related to medication safety. This individual is responsible for identifying key projects related to medication safety and is accountable for coordinating the implementation of these projects system-wide. This individual serves as a liaison to facility pharmacy, nursing and the medical staff leadership personnel.

Minimum Qualifications

- BS in Pharmacy and/or Pharm D
- Pharmacist with hospital pharmacy experience required.
- Individual who is detail-oriented.
- Ability to use independent judgment and communicate effectively.
- Strong leadership ability with superior communication (both verbal and-written) and presentation skills utilizing various types of media.
- Minimum of 3–5 years of hospital experience required.

Required Licensure/Certification Skills

NYS Pharmacy license or licensure eligibility. License or permit required within 6 months of hire.

Vision and Mission

Communicates a clear compelling and inspired vision and sense of organizational purpose. The successful leader takes steps to ensure that the group has the resources, authority, measurable goals, and monitoring systems necessary for high performance and sustained commitment. The effective leader sets realistic but stretch goals, monitors progress and initiates action to effectively enlist others in the movement towards broad organizational and cultural change. Exhibits a clear understanding of health system long-term plan and how all areas contribute to health system vision. This is evidenced by the ability to clearly communicate this vision to staff and co-workers.

Accountability for Results

Achieves challenging objectives, finds better or more efficient ways of accomplishing strategic business results. Takes decisive action, manages financial and human

resources to achieve objectives. Accepts ownership and accountability for decisions and performance outcomes. Anticipates roadblocks and takes decisive and timely action to remain on course to meet objectives. Pushes self and others for success. Achievement oriented, evidenced by examples of personal responsibility in significant achievements

Analytical and Systems Thinking

Utilizes analytical, conceptual and intuitive approaches when planning initiatives, addressing problems, opportunities, and situations. Makes decisions that are data driven whenever appropriate. Sets measurable outcomes for performance. Capitalizes proactively on opportunities by projecting future outcomes and risks.

Change Agent

Embraces and promotes a change-oriented culture, exhibits flexibility to adapt to and work effectively in new situations, and with various individuals or groups. Strives for continuous quality improvements, evaluates current practices against best practices and changes as indicated. Promotes innovation and creativity. Appreciates different and opposing perspectives on an issue, adapts one's approach as the requirements of a situation change, and changes or easily accepts changes in one's own organization or job requirements. Enlists others, and sets personal examples of change, demonstrates expected behavior changes, celebrates successes.

Technical Skills and Job Knowledge

Demonstrates a command of the technical skills and job knowledge necessary to consistently achieve performance objectives. Applies the initiative to remain current with changing technology and operational, clinical, and technical advancements.

Judgment and Integrity and Ethics

Acts honestly and fairly in all interactions with staff and coworkers. Keeps promises and maintains confidences. Complies with organizational policies, both personally and as a manager. Is viewed as a role model by subordinates, peers, and executive management. Takes personal responsibility for actions. Implements departmental audit procedures to insure ethical utilization of resources. Maintains professional business conduct appropriate to the position with a strong commitment to the high standards of business ethics.

Strategic Influence and Communications

The ability to communicate ideas and managerial direction to an audience in a persuasive manner in order to engender support or agreement. It involves targeting information to meet the needs of the audience, anticipating reactions and generating support. Communicates the health system's agenda, spending the necessary time to ensure others fully understand intent, values, objectives and outcomes. Communicates in a compelling and inspired manner, is optimistic, communicates effectively with all levels to include patients, physicians, peers, subordinates, and if applicable, community and external contacts. This is evidenced by subordinates'

and coworkers' awareness of and understanding of the work unit's objectives and performance against objective.

People Skills

Works effectively with others for the common good of the organization; listens effectively, tolerates differences and promotes diversity. Recruits and retains qualified staff to meet unit objectives. Maintains a positive work environment needed to meet annual objectives. Develops staff through one on one coaching and performance appraisal meeting with each employee at least annually and prior to the due date. Accomplishes annual development objectives outlined in the performance appraisal within the assigned deadlines. Also promotes a cooperative work environment by effectively addressing dealing with individuals as well as issues of team morale and productivity. Actively utilizes the health system employee recognition program.

Duties and Responsibilities

- Analyze facility reporting systems to determine their effectiveness in terms of adverse drug event capture, timeliness of reporting, and usefulness of information captured. Create a system wide reporting policy for adverse drug events including standardized definitions.
- Identify best practices for medication safety. Analyze current practices that contribute to medication errors and take proactive steps for prevention. Collaborates with other leaders and facilitates process and system changes and reduce the likelihood of occurrence and recurrence of error.
- Provide project management and overall facilitation for prioritizing and advocating patient safety initiatives related to the design and implementation of systems and processes that support medication safety. Develop project plans and implement in a timely fashion. Responsible for the facilitation of sustainable performance post implementation.
- Review medication safety bulletins, alerts, or publications and conduct an assessment of the medication management systems and process to determine where opportunities for improvement exist. Formulate recommendations, obtain stakeholder support, and work with affected departments to develop an implementation and education plan. Provides education, guidance and assistance to sites, departments, service lines and individuals as it relates to medication safety.
- Participate in facility based root cause analyses. Evaluate systems and process change recommendations on a system wide level to determine where medication safety risks exist and opportunities for improvement are needed. Develop a system wide plan for implementation of recommendations as well as increased awareness of the risks identified with this type of event.
- Perform a system wide analysis of adverse drug events based on data reported from each facility. Identify trends from a system wide and facility basis to determine if corrective actions are needed. Use expert panels to

review adverse drug events. Develops performance measures and reports on a frequent basis.

- Formulate educational sessions for nurses, pharmacists, physicians, and allied health professionals based on reports in the literature, responses to corrective action plans, and recommendations from committee activities.
- Participate on the Safety Institute meetings and update the Committee on the status of initiatives identified in the medication safety plan.
- Establish a system wide working forum on medication safety. Develop and facilitate the implementation of meetings, selection of membership, agenda planning, minutes, follow-up, tracking, and timeliness across all facilities.
- Performance requires the ability to interact consistently and effectively with a large and diverse constituency consisting of members of the pharmacy profession, the nursing profession, medical and dental professionals and administrative staff from all levels of the health system.
- Mentor pharmacy students in the areas of medication safety promotion and regulatory compliance issues.
- Direct involvement in ensuring the ongoing safety of the medical center's technology related to medications (for example, computerized physician order entry system for electronic ordering of patient medications, pharmacy computer system, automated dispensing cabinets, electronic MARs).
- Performs other duties as assigned.

Job Requirements

- Schedule: Full Time

Source: Courtesy of Rochester General Hospital, Rochester General Health System.

*JOB DESCRIPTION #2***Medication Safety Officer****Reports To: Director, Medication Management, Use and Policy****Effective Date: May 17, 2011****Expectation For All Employees**

To provide excellence and innovation in the care of patients, the training of health professionals and the creation and sharing of health knowledge. This institution exists to serve others, and does so through the expression of our core values:

- Respect** To recognize the dignity of every person
- Integrity** To be honest, fair and trustworthy
- Stewardship** To manage resources responsibly
- Excellence** To work at the highest level of performance, with a commitment to continuous improvement

Position Summary

Oversees the Medical Center's Medication Safety Program. Utilizes clinical expertise to facilitate accurate interpretation of clinical events. Work requires knowledge about hands-on medication prescribing, preparation, distribution, administration, and monitoring. Serves as expert, professional resource to Risk Management, Performance Improvement and Pharmacy Department. In addition, work requires excellent presentation, writing, and verbal communication skills.

Essential Duties and Responsibilities

1. Investigates and analyzes reports of adverse drug events (adverse drug reactions, medication errors and near misses).
 - a. Codes all events in Medical Center's Quality Tool, based on The Joint Commission error types and severity levels and ASHP Drug Classification system.
 - b. Works with Quality Tool's Data Analyst to create specific reports based on review of reported events (e.g., error type, error source, high risk, pump setting errors).
 - c. Extracts prescribing errors from Pharmacists Interventions report; analyzes by service, med type, MD, adjustment required per renal function.
 - d. Provides information to appropriate Medical Center Committees or persons as requested or as deemed necessary.
 - e. Uses clinical knowledge and clinical expertise to accurately interpret clinical events and determine contributing factors to errors.
 - f. Works with Risk Management and Patient Safety in review of errors and near misses; recommends groups to work on specific recommendations.

- tions (e.g., soft alerts, hard alerts, point-of-care bar-coding, electronic medication administration records).
4. Leads multidisciplinary medication safety groups.
 - a. Takes leadership role in institutional medication safety/patient safety committees.
 - b. Develop an effective interdisciplinary committee structure to address medication-use safety issues.
 - c. Lead strategic planning for medication-use safety.
 - d. Lead planning activities for the achievement of short-term medication-use safety goals.
 5. Educates Medical Center staff on medication safety.
 - a. Provide effective medication-use safety-related education and/or training to health care professionals, and health care professionals in training.
 - b. Works with patient safety groups to develop computer-based learning modules and other medication safety related education for the Medical Center.
 - c. Provides medication safety related information at various HCP orientations.
 - d. Instructs staff on the mechanics, as well as the importance, of reporting medication safety events (adverse drug reactions, medication errors, and near misses).
 - e. Formulate a plan for any needed education, training, and/or assessment associated with implementation of a new or changed policy or procedure.
 - f. Collaborate with others to develop and deliver education/training involved in the implementation of a changed policy or procedure.
 6. Participates in scholarly/professional activities.
 - a. Conduct medication-use safety and health outcomes research.
 - b. Contribute to the literature on medication-use safety.
 - c. Serve as a peer-reviewer to pharmacy journals.
 - d. Demonstrate involvement in local, state or national pharmacy organization.
 - e. Provide service/leadership on committees of professional organizations.
 - f. Attend professional meetings in the capacity as presenter; committee/council/commission member; and/or elected/appointed officer.
 - g. Provide presentations to health care professionals outside of the Medical Center.

Organizational Duties

1. Communicates appropriately using good interpersonal skills.
 - a. Positive, professional demeanor is projected through verbal and non-verbal communications.

- b. Information for patients and staff is delivered in a manner that is supportive, timely and understandable.
 - c. Interpersonal conflicts are resolved using appropriate methods and organizational resources, including but not limited to Employee Relations Services and Faculty Employee Assistance Program.
 - d. Diverse perspectives are acknowledged; language and behaviors are modeled that build inclusiveness in the work environment.
 - e. Ideas and suggestions are clearly communicated.
 - f. Clarification of communication is requested when appropriate.
2. Serves, manages and supports internal and external customers.
 - a. Privacy is maintained at all times for patient and employee information.
 - b. Actions are initiated to meet or exceed customer/co-workers expectations in delivering service by implementing the "I Make the Difference" philosophy (ownership begins with me; greet customers by making eye contact and smiling; provide positive, professional and prompt responses, e.g. helping visitors find their way; close every interaction with "Is there anything else I can do for you?").
 - c. Appropriate resources throughout the organization are used consistently to meet customer needs.
 - d. Relationships with staff in other work areas are fostered to meet internal and external customer needs.
 - e. Positive working relationships with peers, management and customers are maintained at all times.
 - f. Organizational mission and values of respect, integrity, stewardship and excellence are evident in behaviors.
 3. Participates in performance improvement activities.
 - a. Participation in performance improvement activities and initiatives is on-going.
 - b. Initiative is demonstrated to proactively diagnose and resolve problems.
 - c. Change is met with positive, supportive behavior.
 4. Participates as a team member and is accountable for own work responsibilities.
 - a. Time off is scheduled to avoid disrupting workflow.
 - b. Help is offered to others to solve problems and complete tasks to facilitate communication and positive team dynamics.
 - c. Productive work habits are consistently displayed.
 - d. Accountability for actions and decisions is demonstrated in daily work.
 - e. Feedback is solicited and accepted in a positive manner.
 - f. Constructive input is offered to support the work unit.

Minimum Requirements

Advanced pharmacy degree (Doctor of Pharmacy or Master's degree). Experience: PGY1-required, PGY2 or Fellowship-preferred or equivalent hospital experience (5 years in specific practice area). License/Certification: Virginia State Board of Pharmacy License or within 60 days of hire. Job requires standing for prolonged periods. Proficient communicative, auditory and visual skills; attention to detail and ability to write legibly; ability to lift/push/pull <20 lb. May be exposed to chemicals.

General Information

The above statements are intended to describe the general nature and level of work being performed by individuals assigned to this position. They are not intended to be an exhaustive list of all duties, responsibilities, and skills required of personnel so classified.

Source: Courtesy of University of Virginia Health System.

JOB DESCRIPTION #3

Associate Director, Safety and Quality

Responsibilities

The major areas of responsibility for the Associate Director for Safety and Quality include Hospital Pharmacy's and Ambulatory Care Pharmacy's quality improvement programs, regulatory compliance and staff development. The person in this position also serves as the Medication Safety Officer for the hospital and health sciences system and as such is responsible for coordinating the adverse drug reaction reporting program and assuming a leadership role in the medication error reporting program. This position requires collaboration with health care providers with medication-related responsibilities (e.g., physicians, nurses, pharmacists, quality management, safety and risk management) to measure and improve the safety of the organization's medication system. The person in this position also plays a major role in educating and/or advising pharmacy students and pharmacy residents/fellows as well as other health care students and residents.

Organizational Relationship

The Associate Director for Safety and Quality reports to the Director of Pharmacy Services. Recommendations made as the Medication Safety Officer are also reported to key medical center administrators, the Pharmacy and Therapeutics Committee and the Safety Committee.

Duties Specific to Quality Improvement

Maintains an active and progressive quality improvement program consistent with the goals of the department and the medical center. Responsibilities include:

- Oversee the development/assessment of a pharmacy quality program that monitors and ensures the integrity and safety of the services provided by the department.

- Assimilate the mission statement, goals, and objectives of the department into the departmental quality program.
- Assess departmental compliance with quality indicators through review of audits performed on these indicators.
- Alert management to significant problems identified during audits.
- Forward reports to appropriate individuals.
- Recommend improvement strategies to management regarding issues identified in audits and provide assistance for action plan implementation.
- Review, revise, add and delete audits or indicators based on the needs of the department.

Duties Specific to Medication Safety Officer

The Medication Safety Officer ensures the safety of the organization's medication system and supports an environment dedicated to the safety of our patients, staff, and guests. Responsibilities include:

- Provide direction for the safety of the organization's medication system as chair of the Medication System Review Committee (MSRC).
- Coordinate medication system monitoring program for the ordering, distribution, administration and monitoring of medications used in the hospital. Includes indicator development, auditing, evaluation, and feedback; process improvement recommendations; and staff education initiatives.
- Direct involvement in ensuring the ongoing safety of the medical center's computerized physician order entry system for electronic ordering of patient medications.
- Review medication error/adverse drug event literature, including the Institute for Safe Medication Practices' *Medication Safety Alert!* newsletter, to proactively address potential issues in the medical center.
- Review Medication Occurrence Reports and Adverse Drug Reaction Reports to identify potential system improvements and educational needs.
- Identify potential issues that may warrant root cause analysis (RCA) or failure mode and effects analysis (FMEA) and bring to the attention of the Safety and Risk Management office for authorization.
- Perform a RCA at the direction of the Safety and Risk Management office or the Medical Staff Review Board or a FMEA as recommended by MSRC.
- Oversee the development of new or revision of existing medication-related policy and procedures.
- Provide medication safety information for inclusion in newsletters and other educational efforts for staff education.
- Evaluate and procure commercially available medication- and patient safety-related educational materials including video and audio tapes, computer-assisted instructional programs, printed materials, etc.

- Provide medication safety inservices to medical center staff.
- Develop a structured approach for the post graduate on-the-job training of pharmacist practitioners, pharmacotherapists, pharmacy residents, technicians and managers related to medication safety, incorporating the mission statement, goals, and objectives of the department where appropriate.

Duties Specific to Regulatory Compliance

- Serve as the content expert for The Joint Commission (TJC)/CMS medication management standards and regulations for the medical center.
- Provide medical center staff relevant education on the medication management standards.
- Report deficiencies in departmental compliance to Director of Pharmacy.
- Report deficiencies in medical center compliance to TJC/CMS Compliance Committee.
- Recommend improvements to achieve compliance.
- Ensure departmental and hospital compliance with all TJC and CMS requirements.

Duties Specific to Staff Development

- Oversee departmental training programs for new pharmacotherapists, pharmacists and technicians.
- Ensure maintenance of training files for all employees, documenting participation and adherence to Illinois laws, accreditation organizations and departmental policy.

Educational Expectations

- Participate in the education of nursing staff, medical staff, and all members of the healthcare team.
- Participate in hospital and departmental staff development by designing, evaluating and providing inservices, continuing education programs and by serving as a preceptor and role model.
- Participate in the education of Pharm.D. students, PGY1 and PGY2 residents, fellows and other pharmacy staff by serving as a preceptor and role model as defined by the guidelines and requirements of the Department of Pharmacy Practice.

Research and Scholarship Expectations

- Facilitate the advancement of knowledge in health care by participating in research and scholarly activities.
- Attend and actively participate in departmental, college and team meetings.
- Represent the department on university and medical center committees as assigned.

- Participate in public service events as available (e.g., brown bags, community education, etc).

Education and Training

Graduate of approved 5- or 6-year pharmacy program. Licensed as a pharmacist by the State of Illinois or eligible for licensure. Post-graduate education (Pharm.D. or M.S.) required. At least 2 years experience as a clinical staff pharmacist, clinical pharmacist, or staff development pharmacist required. Must have a philosophy of practice in accordance with the department. This individual must be able and willing to participate in the educational missions of the college of pharmacy, pharmacy department, and the medical center.

Source: Courtesy of the University of Illinois at Chicago Medical Center, Department of Hospital Pharmacy Services.

Appendix 1-C. Alignment of MSO Responsibilities with Organizational Strategic Plan

Percent Time	Activity Detail	Departments Supported	Support of Strategic Plan
10%	<p>Responsibility #1. Identify best practices for medication safety across the organization. Facilitate medication process quality improvement and assurance related to medication safety indicators.</p> <ul style="list-style-type: none"> ■ System support: EMR design/validation ■ Participated in 90% of validation sessions that touched the medication use process ■ Participated in all FMEAs for the new medication processes ■ Facilitated two critical issues sessions during go-live ■ Provide evidence based support, best safety practice guidance, and organizational lessons learned to design/build (go-live and on-going) ■ Data analysis during go-live and post-go-live 	<ul style="list-style-type: none"> ■ Pharmacy ■ Nursing ■ OR ■ L&D ■ System-wide IT ■ Medical staff ■ 6 Sigma 	<ul style="list-style-type: none"> ■ Goal: care safety, community of caregivers, service culture ■ Critical success factors: public accountability ■ Strategic areas of improvement: reduce complications; improve on TJC, NPSG, and QI
30%	<ul style="list-style-type: none"> ■ 6 Sigma projects: Anticoagulation, Pump Programming, Palliative Care ■ Participated in process mapping (Anticoagulation) ■ Literature evaluation for best practice (Anticoagulation, Pump Programming, Palliative Care) ■ Participated in solution development (Anticoagulation) ■ Physician outreach (Anticoagulation) ■ Managed the measurement plan (Anticoagulation, Pump Programming) ■ Performed data analysis (Anticoagulation, Pump Programming) ■ Designed and performed the financial analysis (Anticoagulation) ■ Co-authored business plan (Anticoagulation) ■ Educated and communicated the plan through medical staff, pharmacy, and hospital committees (Anticoagulation, Pump Programming) ■ Served as temporary co-process owner (Anticoagulation) 	<ul style="list-style-type: none"> ■ Pharmacy ■ Nursing ■ OR ■ System-wide IT ■ Medical staff ■ 6 Sigma 	<ul style="list-style-type: none"> ■ Goal: care safety, service culture ■ Critical success factors: public accountability, financial stewardship ■ Strategic areas of improvement: reduce complications; improve on TJC, NPSG, and QI

continued

30%	<p>Adverse Drug Event (ADE) subcommittee</p> <ul style="list-style-type: none"> ■ Develop content for agenda ■ Organize ad hoc work groups to address issues identified through voluntary reporting, TJC standards, and Institute of Safe Medication Practices recommendations. ■ Literature evaluation for best practice ■ Continual maintenance of IV Drug Administration policy content and web application ■ Participate in medication management policy content development for the medical center ■ Coordinate communication between disciplines about policy/process changes. 	<ul style="list-style-type: none"> ■ Medical staff ■ Nursing ■ Pharmacy <p>■ Goal: quality care, care safety, community of care givers</p> <p>■ Critical success factors: public accountability, physician/provider alignment</p> <p>■ Strategic areas of improvement: reduce complications, improve on TJC NPSG and QI</p>
Analyze current practices that contribute to medication errors and take pro-active steps for prevention.		
5%	<p>Lead root cause analysis (RCA) surrounding medication events</p> <ul style="list-style-type: none"> ■ Participate in fact gathering/staff interviews ■ Literature evaluation to identify best practices, if any ■ Facilitate meetings ■ Collate idea generation from RCA ■ Develop implementation plan ■ Coordinate measurements 	<ul style="list-style-type: none"> ■ Hospital administration ■ Inpatient nursing units ■ Procedural areas ■ Pharmacy <p>■ Goal: care safety</p> <p>■ Critical success factors: public accountability</p> <p>■ Strategic areas of improvement: reduce complications</p>
5%	<p>Lead/and or facilitate FMEAs and process redesign for high-risk medication processes</p> <ul style="list-style-type: none"> ■ Idea generation ■ Facilitate meetings ■ Coordinate development of mitigation strategies ■ Participate on behalf of patient safety in other projects' FMEAs 	<ul style="list-style-type: none"> ■ Medical staff ■ Pharmacy ■ Nursing ■ New patient care building committee ■ Outpatient medical group ■ System-wide IT <p>■ Goal: care safety</p> <p>■ Critical success factors: public accountability</p> <p>■ Strategic areas of improvement: reduce complications; improve on TJC, NPSG, and QI</p>

continued

5%	<p>Identify trends and opportunities for improvement from medication data entered into the event reporting system</p> <ul style="list-style-type: none"> ■ Generate reports ■ Perform data analysis 	<ul style="list-style-type: none"> ■ Nursing ■ Pharmacy ■ Medical staff 	<ul style="list-style-type: none"> ■ Goal: care safety ■ Critical success factors: public accountability ■ Strategic areas of improvement: reduce complications; improve on TJC, NPSG, and QI
Advance and support the patient safety plan and the culture of safety throughout the medical center.			
5%	<p>Provide summaries of medication error reporting, outcomes of ADE reduction projects, and communicate ongoing initiatives to promote medication safety in the microsystem</p> <ul style="list-style-type: none"> ■ Quarterly bring data to Professional Nursing Congress Pharmacy and Therapeutics, Professional Staff Quality Improvement, Quality Safety Board ■ Attend the clinical educator's meeting monthly ■ Medical Executive committee once per year ■ Round with unit councils ■ "Lifesaver" recognition letters to staff who make "great catches" 	<ul style="list-style-type: none"> ■ Medical staff ■ Nursing ■ Pharmacy ■ Hospital administration 	<ul style="list-style-type: none"> ■ Goal: care safety, community of care givers ■ Critical success factors: public accountability, physician/provider alignment, community of care givers ■ Strategic areas of improvement: reduce complications; improve on TJC, NPSG, and QI
10%	<p>Participate in safety rounds, tracers to identify medication safety opportunities.</p> <ul style="list-style-type: none"> ■ Interact with both management and front-line staff ■ Listen to safety concerns raised ■ Inquire about key medication safety issues ■ Validate processes recently implemented ■ Identify gaps in achieving TJC medication management standards/safety goals 	<ul style="list-style-type: none"> ■ Medical center ■ Skilled nursing facility 	<ul style="list-style-type: none"> ■ Goal: care safety ■ Critical success factors: public accountability, community of care givers ■ Strategic areas of improvement: reduce complications; improve on TJC, NPSG, and QI

EMR, electronic medical record; FMEA, failure mode and effects analysis; IT, information technology; IV, intravenous; L&D, labor and delivery; OR, operating room; NPSG, National Patient Safety Goals; QI, quality improvement; SBAR, situation background, assessment, recommendation; TJC, The Joint Commission.
Source: Courtesy of OSF Saint Francis Medical Center, Quality/Safety Department, Peoria, IL.